K091031

NOV 17 2009

510(k) Summary

Pioneer Surgical Technology
Pioneer FortrOss Bone Void Filler

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Pioneer Surgical Technology 375 River Park Circle Marquette, MI 49855 Telephone: +1 (906) 226-4812 Fax: +1 (906) 226-4459
Official Contact:	Jonathan Gilbert
Representative/Consultant:	David J. Collette, MD Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 email: dcollette@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Pioneer FortrOss Bone Void Filler
Common Name:	Bone Void Filler
Classification Regulations:	Filler, Bone Void, Calcium Compound 21 CFR 880.3045 Class II (special controls)
Product Code:	MQV
Classification Panel:	Orthopaedic and Rehabilitation Devices Panel
Reviewing Branch:	Restorative Devices Branch

INTENDED USE

Pioneer FortrOss Bone Void Filler is indicated for bony voids or gaps that are not intrinsic to the stability of bony structure. These defects may be surgically created osseous defects or defects created from traumatic injury to the bone. The product is indicated to be used in the posterolateral spine in conjunction with bone marrow aspirate and autograft bone. The product

provides a bone void filler that resorbs and is replaced with bone during the healing process.

DEVICE DESCRIPTION

Pioneer FortrOss Bone Void Filler is a porous calcium phosphate material mixed with a porcine gelatin carrier. The product is an osteoconductive scaffold mixed with a gelatin carrier for use in repairing bony defects in spinal indications.

EQUIVALENCE TO MARKETED DEVICES

Pioneer FortrOss Bone Void Filler is identical in composition and performance to Pioneer BVF-E cleared (K081558). Predicate devices with similar characteristics, which may include ceramic materials, porcine gelatin carrier, porous structure, and presentation are cited below.

Devices to Which Substantial Equivalence is Claimed:

K081558 – Pioneer Surgical NanOss BVF-E
K082575 – Actifuse™ Bone Graft Substitute
K050798 – Formagraft™ Collagen Bone Graft Matrix
K032288 – Vitoss® Scaffold Foam

The comparisons and testing conducted on FortrOss Bone Void Filler demonstrate that the device is substantially equivalent to other bone void fillers currently in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Pioneer Surgical Technology
% PaxMed International, LLC
David J. Collette, M.D.
11234 El Camino Real, Suite 200
San Diego, CA 92130

NOV 17 2009

Re: K091031
Trade/Device Name: Pioneer FortrOss Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: October 29, 2009
Received: October 30, 2009

Dear Dr. Collette:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K091031

Device Name: Pioneer FortrOss Bone Void Filler

Indications for Use:

Pioneer FortrOss Bone Void Filler is indicated for bony voids or gaps that are not intrinsic to the stability of bony structure. These defects may be surgically created osseous defects or defects created from traumatic injury to the bone. The product is indicated to be used in the posterolateral spine in conjunction with bone marrow aspirate and autograft bone. The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091031